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Application Number 10/666,288
Amendment Dated 02/13/2007
Reply to Office Action of 09/13/2006

In the Drawings

The attached sheet of drawings includes a change to Figure 2. This sheet replaces the original sheet including Figure 2.

Attachment: Replacement Sheet

Annotated Sheet Showing Changes

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REMARKS

Section I – Extension of Time

A petition for extension of time is being filed concurrently herewith.

Section II - Amendments to the specification

Applicant has amended paragraph [0045] of the specification to delete the "not shown" statements regarding the distal and proximal openings. No new matter has been introduced.

Section III - Amendments to the drawings

In amended Figure 2, the size of the distal opening has been increased, as described in paragraph [0045] of the specification as originally filed. No new matter has been introduced.

Section IV - Claim Status

The above-identified application has been carefully reviewed in light of the Office Action mailed on September 13, 2006.

Claims 18-28, 30, 53 and 55 remain in this application. Claims 21, 24, 25, 28 and 35 were previously presented and claims 18-20, 22, 23, 26, 27, 30 and 53 are currently amended. Claims 1-17, 29, 32-52 and 54 were previously cancelled and claim 31 is presently cancelled.

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Section V - Claim rejection under 35 USC 112.

The Examiner has rejected claim 26 due to insufficient antecedent basis for the term "auxiliary radiopaque marking". Amended claim 26 does not include this term and the Applicant respectfully requests that this rejection of claim 26 be withdrawn. Also, the claim dependency of claim 53 has been corrected.

Section VI - Claim rejections under 35 USC 103

The Examiner has rejected claims 18-21, 24-28, 30, 53 and 55 as being unpatentable over Eggers et al. (6,032,674) (hereinafter "Eggers") in view of Shah et al. (6,565,562) (hereinafter "Shah"). In addition, claims 22-23 and 31 have been rejected as being unpatentable over Eggers et al. in view of Shah et al. and further in view of Lesh et al. (6,650,923) (hereinafter "Lesh").

Amended claim 18 includes the following limitation:

delivering a radiopaque fluid outside of said device through said lumen and said openings in a manner such that said radiopaque fluid has a substantially uniform distribution along said distal region;

This feature is described in applicant's specification as originally filed, for example at paragraph [0045].

Applicant respectfully submits that none of the documents cited by the Examiner either teach or suggest delivering a radiopaque fluid outside of a device through a lumen and at least two openings in a manner such that the radiopaque fluid has a substantially longitudinally uniform distribution substantially along a distal region of the device. Eggers discloses a device and a method for creating channels through the myocardium (the muscular layer located at the periphery of

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the heart) using radio-frequency electrical current. Shah describes a method for creating a hole in an atrial septum by delivering radiofrequency energy using an active electrode in conjunction with a ground plate. Neither Eggers nor Shah disclose delivery of a radiopaque fluid for assessing the position of the device. Lesh discloses using a needle to pierce a hole through an atrial septum. Lesh further discloses injecting contrast through the needle to confirm that the distal end of the needle has traversed the septum. However, Lesh neither teaches nor suggests applicant's invention as claimed, as described further herein below.

In opposition to the present invention, the device disclosed in Lesh includes only a hollow needle through which the radiopaque fluid is delivered (Col 7, lines 26-30). More specifically, Lesh teaches delivering contrast media via the lumen of a transseptal needle, which typically has an open distal tip. This would cause the contrast to be delivered substantially distally relative to the needle. If the distal tip of the needle were to be positioned substantially adjacent to a tissue surface, for example adjacent to the fossa ovalis of the atrial septum prior to piercing the septum, such that the distal tip of the needle were to be occluded by tissue, it would be difficult to inject contrast in order to assess the position of the device.

Thus, Lesh does not teach nor suggest distributing the fluid through more than one opening such that the fluid is distributed substantially uniformly. Such a uniform distribution has many advantages including, but not limited to, reducing the radiation to which a patient may be exposed. By distributing the fluid substantially uniformly, it may be possible to visually assess the position of the device under X-ray fluoroscopy with reduced X-ray exposure time. Since the fluid is distributed substantially uniformly in the claimed invention, the contrast between the fluid and surrounding tissues is increased at a faster rate, which therefore requires less radiation in order to assess the position of the active electrode. Furthermore, the invention as claimed facilitates the even distribution of contrast adjacent to the distal region of the device, which may allow for

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improved visualization using less contrast fluid. Injecting less contrast fluid is beneficial to the patient as it results in less foreign material being injected into the body. In addition, and in contrast to the disclosure of Lesh, applicant's invention as claimed provides the novel and non-obvious advantage of allowing for injection of contrast even with the tip of the device located adjacent to a tissue surface, by distributing the fluid longitudinally substantially adjacent the distal region of the device.

Claims 19, 20, 22, 23, 26, 27, 30 and 53 have been amended in order to correct for minor typographical errors, to correct for antecedents in view of applicant's amendments to claim 18 and to clarify applicant's invention. No new matter has been added by any amendments made in the present response.

Claims 19-28, 30, 53 and 55 all depend directly or indirectly from claim 18 and as such include all the limitations of this base claim. Accordingly, applicant respectfully submits that these claims distinguish over the art cited by the Examiner for the same reasons as those expressed hereinabove with respect to claim 18.

It is respectfully submitted that when the rejection of the claims is reviewed in light of the present amendments as well as applicant's arguments, the invention should be considered patentably distinguished over the cited references. It is now believed the above application is in condition for allowance and such action would be appreciated.

Very respectfully submitted.

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AMENDMENT DATED FEB. 13, 2007
REPLY TO OFFICE ACTION OF SEPTEMBER 13, 2006
ANNOTATED MARKED UP DRAWINGS

Figure 2

